UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,335	07/03/2003	Walter A. Zohmann	10012.7	5090

21999 7590 01/19/2010

KIRTON AND MCCONKIE
60 EAST SOUTH TEMPLE,
SUITE 1800
SALT LAKE CITY, UT 84111

EXAMINER	
CAMPBELL, VICTORIA P	
ART UNIT	**PAPER NUMBER**
3763	

MAIL DATE	DELIVERY MODE
01/19/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/613,335	ZOHMANN, WALTER A.	
	Examiner	Art Unit	
	VICTORIA P. CAMPBELL	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the initial Office Action following the third Request for Continued Examination based on the 10/613335 application filed September 3, 2003. Claims 1-12 as amended and newly presented December 11, 2009 are currently pending and considered below.

Claim Objections

1. Claims 1-12 objected to because of the following informalities: the claims inconsistently refer to "facial" compartments as well as "fascial" compartments, which are two entirely different anatomical areas. The examiner requests the claims, as well as the specification, are thoroughly inspected to ensure all instances of the term "fascial" are spelled properly. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 5, 7, and 10-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. Regarding the above claims, applicant is relying upon Page 8, lines 14-15 to support the new claim limitation of "spaced at intervals within two millimeters of each other" and “spaced within one millimeter of each other”. However, there is insufficient support for this limitation in the specification as filed. The specification as filed reads "Fenestrations 20 are preferably located *within one to two millimeters* [...] of each other for this purpose." The examiner notes that the phrase "within one to two millimeters" is equivalent to stating "*between* one and two millimeters" of each other. Therefore, applicant lacks antecedent basis for the claimed range “within two millimeters” because that claimed range is equivalent to stating "from zero to two millimeters" and applicant does not have antecedent basis for the range of zero to one millimeter. Furthermore, the phrase "within one millimeter" is equivalent to “from zero to one millimeter”, which, as stated above, the applicant does not have antecedent basis for in the specification as filed.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 2, 7-10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 5,250,035 to Smith et al in view of USPGPub 2002/0123723 to Sorenson et al.

Regarding the above claims, Smith et al teach a hollow needle (28), a needle hub (32) having a hollow interior (38) at the proximate end of the hollow needle (34), and a stylet cap (60) on a proximal end of a stylet (68), the stylet being freely movable within the needle (Col. 4, lines 43-45), wherein the stylet cap creates a releasably secure fit with the needle hub (66 received into 38). Smith et al also teach the process of identifying the dermal area of the patient (Col. 3, lines 27-29), inserting and advancing the needle into the dermal area (Col. 4, lines 63-67), withdrawing the stylet (Col. 5, lines 6-8), and injecting an anesthetic (Col. 4, lines 58-60), wherein the needle further comprises a needle hub (32), and wherein withdrawal of the stylet comprising observing a backflow of fluid (Col. 5, lines 8-15).

Smith et al fail to teach or disclose the hollow needle having a plurality of fenestrations longitudinally disposed along alternate sides of the needle, spaced at intervals within two millimeters of each other or one millimeter of each other. However, Sorenson et al teach a plurality of fenestrations (85) disposed on alternate sides of the needle (Fig. 1) at the distal delivery portion of the device (50). Regarding the spacing of the fenestrations, the examiner notes that it would have been obvious to one having

ordinary skill in the art at the time the invention was made to space the fenestrations within two millimeters of each other since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Furthermore, the examiner notes that the drawings can not be relied upon to show that the fenestrations are more than 5 mm apart because drawings, unless noted, are not treated as drawn to scale and therefore the spacing may be smaller or larger than depicted in the figures of Sorenson et al. Additionally, the examiner notes that the two millimeter spacing could also be around the circumference of the needle, and that it could also be possible for the fenestrations of Sorenson et al to fall within two millimeters of one another in that direction.

Furthermore, although Smith et al do not explicitly disclose inserting the needle through the fascial member and locating at least once of the fenestrations within the fascial compartment, the examiner notes that the device of Smith et al is capable of performing the advancement step as described in the claims, and therefore it would have been obvious to attempt the method of injection in a fascial compartment with the device of Smith et al and Sorenson et al as described above.

Smith et al and Sorenson et al are analogous art because they are from the same field of endeavor/problem solving area of medical needles. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Smith et al and Sorenson et al before him or her to modify the needle of Smith et al to include the multiple distally located apertures of Sorenson et al because

doing so provides a wider distribution of fluid than with a single opening while still limiting distribution to a treatment site (Sorenson et al, Paragraphs [0033] and [0036]). Therefore, it would have been obvious to combine Smith et al with Sorenson et al to obtain the invention in the instant claims.

8. Claims 3-6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al and Sorenson et al in further view of USPGPub 2002/055715 to Young et al.

Regarding claims 3 and 4, Smith et al and Sorenson et al disclose the invention of claims 1 and 2 as described above, but fail to teach or disclose a fenestration indicator or a magnifying window on the needle hub. However, Young et al teach a needle hub (10) containing both a fenestration indicator (16) and a magnifier (17).

Regarding claims 5 and 6, Smith et al teach a hollow needle (28) being bounded by an occluded tip (72), a needle hub (32) at the proximate end of the hollow needle (34), and a stylet cap (60) on a proximal end of a stylet (68), wherein the stylet cap creates a releasably secure fit with the needle hub (66 received into 38), the stylet being freely movable within the needle (Col. 4, lines 43-45), wherein the stylet occludes the fenestrations (Fig. 11).

Smith et al fail to teach the needle having a plurality of longitudinally disposed fenestrations. Smith et al also fail to teach the needle hub having at least one fenestration indicator and a magnifying window.

Sorenson et al teach a plurality of fenestrations (85) disposed on alternate sides of the needle (Fig. 1). Combination of Smith et al and Sorenson et al is reasoned above.

Young et al teach a needle hub (10) containing both a fenestration indicator (16) and a magnifier (17).

Smith et al, Sorenson et al, and Young et al are analogous art because they are from the same field of endeavor/problem solving area of medical needles. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Smith et al, Sorenson et al, and Young et al before him or her to modify the needle system of Smith et al and Sorenson et al to include the fenestration indicator and magnifying window of Young et al because the indicator allows the user to properly orient the hub during low light conditions (Young et al, Paragraph [0031]) and the magnifier decreases the recognition time from when the fluid first enters the hub (Young et al, Abstract). Therefore, it would have been obvious to combine Smith et al and Sorenson et al with Young et al to obtain the invention in the instant claims.

Regarding claim 11, please see the rejection above regarding claims 10 and 12.

Response to Arguments

9. Applicant's arguments filed December 11, 2009 have been fully considered but they are not persuasive.

10. In response to applicant's arguments beginning on page 1 and ending half way down page two, the applicant appears to be arguing that Smith et al is nonanalogous

art. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, while the device of Smith et al may be used in a different application, it's function--to deliver fluid to an area of the body after ensuring the needle is properly placed--is generally the same as that of the instant invention, and therefore one having ordinary skill in the art at the time of invention would recognize the applicability of the device of Smith et al to the function of the instant invention.

11. In response to applicant's arguments regarding the spacing of the fenestrations of Sorenson et al, the examiner draws applicant's attention to where this limitation was addressed in the rejection above for explanation.

12. In response to applicant's argument that the limitation "to induce an efflux of local anesthetic into said fascial compartment while minimizing flow of anesthetic outside the boundaries of the fascial compartment and a corresponding anesthetic block at said affected peripheral nerve" is not taught by the prior art, the examiner disagrees and notes that, as noted in applicant's specification on Page 8, line 18 through page 9, line 11, as well as applicant's most recent remarks on page 3, this limitation is fulfilled simply by placement of the needle having multiple fenestrations having at least one of said fenestrations located in said fascial compartment, which is accomplished by the references of record as described in the above rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763